

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

[name and address redacted]

RE: Advisory Opinion No. CMS-AO-2008-02

Dear [name redacted]:

We are writing in response to your request for an advisory opinion on behalf of the physician owners (the “Physicians” or the “Requestors”) of [name redacted] (the “Diagnostic Center”), concerning whether a certain financial arrangement would comply with the physician self-referral statute, section 1877 of the Social Security Act (the “Act”). Specifically, you seek to obtain a determination that the Physicians may refer patients to the Diagnostic Center for designated health services (“DHS”), and the Diagnostic Center may bill and submit claims for such services, because any Physician ownership or investment interest in the Diagnostic Center would satisfy the rural provider exception found in section 1877(d)(2) of the Act.

You have certified that all of the information provided in your request, including all supplementary materials and documentation, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties regarding the arrangement (the “Arrangement”). In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of this information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this advisory opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplementary submissions, and for the reasons set forth below, we conclude that the Arrangement would satisfy the rural provider exception to the prohibition against physician self-referral, provided that the DHS for which Medicare patients are referred to the Diagnostic Center by the Physicians continue to be furnished outside the boundaries of a Metropolitan Statistical Area (“MSA”) and that no less than 75 percent of the DHS furnished by the Diagnostic Center continue to be furnished to individuals residing outside a MSA.

This opinion may not be relied on by any persons other than the Requestors of this opinion (that is, the Physicians).

## **I. FACTUAL BACKGROUND**

The Diagnostic Center is a limited liability company that opened for business in [month and year redacted]. All but one of the Requestors has an ownership interest in the Diagnostic Center.<sup>1</sup> The Diagnostic Center offers a variety of services, including physician consultation on a walk-in, urgent care basis, as well as ancillary services such as clinical laboratory services and diagnostic radiology services (including on-site magnetic resonance imaging provided by a visiting van). According to the Requestors, many of the Physicians have made and will continue to make referrals of Medicare patients to the Diagnostic Center for the aforementioned services.<sup>2</sup>

The Diagnostic Center is located in [location redacted], which is in [location redacted]. The Requestors certified that all of the DHS performed by the Diagnostic Center since it opened in [month and year redacted] have been furnished outside a MSA. Requestors further certified that, on an annual basis, at least 75 percent of the DHS provided by the Diagnostic Center to date have been furnished to individuals residing outside of a MSA. Finally, Requestors certified that the DHS performed by the Diagnostic Center will continue to be furnished outside a MSA, and that at least 75 percent of the DHS furnished by the Diagnostic Center will continue, on an annual basis, to be furnished to individuals residing outside of a MSA.

## **II. LEGAL ANALYSIS**

### **A. Law and Regulations**

Under the physician self-referral statute, section 1877 of the Act (42 U.S.C. §1395nn), a physician may not refer a Medicare patient for DHS to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies.<sup>3</sup> Section 1877 also prohibits the entity furnishing the DHS from submitting claims to Medicare, the beneficiary, or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

The rural provider exception in section 1877(d)(2) of the Act is potentially applicable to the Requestors' referrals for DHS furnished by the Diagnostic Center. This exception

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<sup>1</sup> One of the Requestors is a physician who is not currently an investor in the Diagnostic Center, but intends to become an investor if we issue a favorable advisory opinion.

<sup>2</sup> The Requestors also state that many of the Physicians refer patients to and perform surgery at [name redacted] ("Surgery Center"), a facility adjoining the Diagnostic Center. We express no opinion about the arrangement between the Physicians and the Surgery Center.

<sup>3</sup> In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. 42 U.S.C. §1396b(s).

applies “. . . [i]n the case of DHS furnished in a rural area (as defined in section 1886(d)(2)(D)) by an entity, if substantially all of the DHS furnished by such entity are furnished to individuals residing in such a rural area.” The rural provider exception is codified in our regulations in 42 C.F.R. §411.356(c)(1). In 42 C.F.R. §411.356(c)(1), we have interpreted “substantially all” to mean not less than 75 percent of the DHS that an entity furnishes to residents of a rural area. A rural area is defined at 42 C.F.R. §411.351 as an area that is not an urban area as defined at §412.62(f)(1)(ii). Section 412.62(f)(1)(ii) defines an urban area as a MSA or a New England County Metropolitan Area (as defined by the Office of Management and Budget (“OMB”)), or as certain specified New England counties.

## **B. Analysis**

The rural provider exception in section 1877(d)(2) of the Act applies only to ownership or investment interests in a DHS entity.<sup>4</sup> An ownership or investment interest in the Diagnostic Center must pass a two-part test in order to qualify for the rural provider exception.

The first requirement of the rural provider exception is that the DHS must be furnished in a rural area. The Diagnostic Center is located in [county and state redacted], an area that OMB has continually designated a “micropolitan statistical area” since before the Diagnostic Center opened for business.<sup>5</sup> Because [county redacted] is not listed as a MSA or a constituent county of a MSA, by definition, it is considered to be a rural area for purposes of the physician self-referral rules.<sup>6</sup> The Requestors have certified that all of the DHS furnished by the Diagnostic Center have been, and will continue to be, furnished outside a MSA. Based on the Requestors’ certifications, we conclude that the Arrangement satisfies the first requirement of the rural provider exception.<sup>7</sup> Of course, if

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<sup>4</sup> The rural provider exception, like the other ownership exceptions in 42 C.F.R. §411.356, protects remuneration to a physician that is based on the physician’s ownership or investment interest. If an owner/investor physician who refers a Medicare beneficiary to an entity for DHS also has a compensation arrangement with the entity, the compensation arrangement must be protected by an exception for compensation arrangements in order for the compensation arrangement to comply with the physician self-referral statute and regulations. Here, the Requestors certified that no compensation arrangements exist between the Physicians and the Diagnostic Center.

<sup>5</sup> See OMB Bulletin Nos. 06-01 (Dec. 5, 2005), 07-01 (Dec. 18, 2006), and 08-01 (Nov. 20, 2007), available on the OMB website at <http://www.whitehouse.gov/omb>.

<sup>6</sup> See 72 FR at 51012, 51042 (Sept. 5, 2007).

<sup>7</sup> For purposes of this advisory opinion, we rely on your certifications as to the location where services have been and will be furnished by the Diagnostic Center. If the DHS are not, or cease to be, furnished outside a MSA, this opinion is, or will be, without force and effect.

at some time, [county redacted] should be considered part of a MSA, the rural provider exception would no longer be available to protect the Physicians' referrals of DHS and the Diagnostic Center's corresponding billing and claims submission.

The second requirement of the rural provider exception is that substantially all of the DHS furnished by an entity (that is, at least 75 percent) must be furnished to individuals residing in a rural area. The Requestors certified that, on an annual basis, at least 75 percent of the DHS provided by the Diagnostic Center have been, and will continue to be, furnished to individuals residing outside of a MSA. Based on the Requestors' certification, we conclude that the Diagnostic Center meets the second prong of the rural provider exception.<sup>8</sup> We caution, however, that the "substantially all" test is an ongoing requirement. Therefore, to remain within the rural provider exception, it is necessary that substantially all (that is, at least 75 percent) of the DHS continue to be furnished to patients who reside in a rural area.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement between the Requestors and the Diagnostic Center meets the criteria set forth in the rural provider exception in section 1877(d)(2) of the Act and 42 C.F.R. §411.356(c)(1).<sup>9</sup>

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon, by any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requestor of this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state or local statute, rule, regulation, ordinance or other law that may be applicable to the Requestors, including, without limitation, the Federal anti-kickback statute, section 1128B(b) of the Act (42 U.S.C. §1320a-7b(b)).

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<sup>8</sup> For purposes of this advisory opinion, we rely on your certifications as to the residence of individuals who receive services furnished by the Diagnostic Center. If the "75 percent test" is not, or ceases to be, satisfied, this opinion is, or will be, without force and effect.

<sup>9</sup> We express no opinion with regard to the requirements of the Federal anti-kickback statute, section 1128B(b) of the Act (42 U.S.C. §1320a-7b(b)).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services. CMS reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify or terminate this opinion.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth in 42 C.F.R. §§ 411.370 through 411.389.

Sincerely,

Jeffrey B. Rich, M.D.  
Director  
Center for Medicare Management